

## § 520.1615

(ii) *Indications for use*—(A) For the treatment of flea infestations on dogs and puppies 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(1)(i)(B) of this section with either flavored lufenuron tablets as in § 520.1288(c)(1) of this chapter or flavored milbemycin and lufenuron tablets as in § 520.1446(d)(1) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

(2) *Cats*—(i) *Amount*—(A) One 11.4-mg tablet, as needed, for use as in paragraph (d)(2)(ii)(A) of this section.

(B) One 11.4-mg tablet, once or twice weekly, for use as in paragraph (d)(2)(ii)(B) of this section.

(ii) *Indications for use*—(A) For the treatment of flea infestations on cats and kittens 4 weeks of age and older and 2 lbs of body weight or greater.

(B) The concurrent use of nitenpyram tablets as in paragraph (d)(2)(i)(B) of this section with flavored lufenuron tablets as in § 520.1288(c)(2) of this chapter is indicated to kill adult fleas and prevent flea eggs from hatching.

[68 FR 51906, Aug. 29, 2003]

## § 520.1615 Omeprazole.

(a) *Specifications*. Each gram of paste contains 0.37 gram omeprazole.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Special considerations*. When labeled for use as in paragraph (d)(2)(i) of this section, product labeling shall bear: “Federal law restricts this drug to use by or on the order of a licensed veterinarian.”

(d) *Conditions of use in horses*—(1) *Amount*—(i) For treatment of gastric ulcers, 1.8 milligrams per pound (mg/lb) of body weight (4 milligrams per kilogram (mg/kg)) once daily for 4 weeks. For prevention of recurrence of gastric ulcers, 0.9 mg/lb of body weight (2 mg/kg) once daily for at least an additional 4 weeks.

(ii) For prevention of gastric ulcers using the premarked syringe, one dose per day for 8 or 28 days. Each dose delivers at least 1 mg/kg of body weight. Horses over 1,200 lb body weight should receive two doses per day.

(2) *Indications for use*. (i) For treatment and prevention of recurrence of

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gastric ulcers in horses and foals 4 weeks of age and older.

(ii) For prevention of gastric ulcers in horses.

(3) *Limitations*. Do not use in horses intended for human consumption.

[69 FR 13220, Mar. 22, 2004, as amended at 71 FR 59374, Oct. 10, 2006]

## § 520.1616 Orbifloxacin tablets.

(a) *Specifications*. Each tablet contains 5.7, 22.7, or 68 milligrams (mg) orbifloxacin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats*—(1) *Amount*. 2.5 to 7.5 mg per kilogram body weight once daily.

(2) *Indications for use*. For management of diseases associated with bacteria susceptible to orbifloxacin.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food producing animals.

[71 FR 14643, Mar. 23, 2006, as amended at 75 FR 26646, May 12, 2010]

## § 520.1618 Orbifloxacin suspension.

(a) *Specifications*. Each milliliter of suspension contains 30 milligrams (mg) orbifloxacin.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

(d) *Conditions of use*—(1) *Dogs*—(i) *Amount*. 1.1 to 3.4 mg/lb (2.5 to 7.5 mg/kg) of body weight once daily.

(ii) *Indications for use*. For the treatment of urinary tract infections (cystitis) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Proteus mirabilis*, *Escherichia coli*, and *Enterococcus faecalis* and skin and soft tissue infections (wounds and abscesses) in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*, *Staphylococcus aureus*, coagulase-positive staphylococci, *Pasteurella multocida*, *Proteus mirabilis*, *Pseudomonas* spp., *Klebsiella pneumoniae*, *E. coli*, *Enterobacter* spp., *Citrobacter* spp., *E. faecalis*,  $\beta$ -hemolytic